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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/737,403

12/16/2003

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EXAMINER

WOOLWINE, SAMUEL C

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

07/07/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/737,403	<b>Applicant(s)</b> WILLSON ET AL.	
	<b>Examiner</b> SAMUEL C. WOOLWINE	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5, 11, 12 and 14-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5, 11, 12 and 14-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status***

Applicant's response filed 04/06/2010 is acknowledged.

Despite Applicant's amendments to the claims, issues remain with regard to 35 USC 112, 2<sup>nd</sup> paragraph. Some of the previous issues under this rejection have been corrected by the amendments to the claims, but other issues remain and some new issues have been created because of Applicant's amendment to claim 5. Any issues not discussed in the rejection below may be considered withdrawn as no longer applicable.

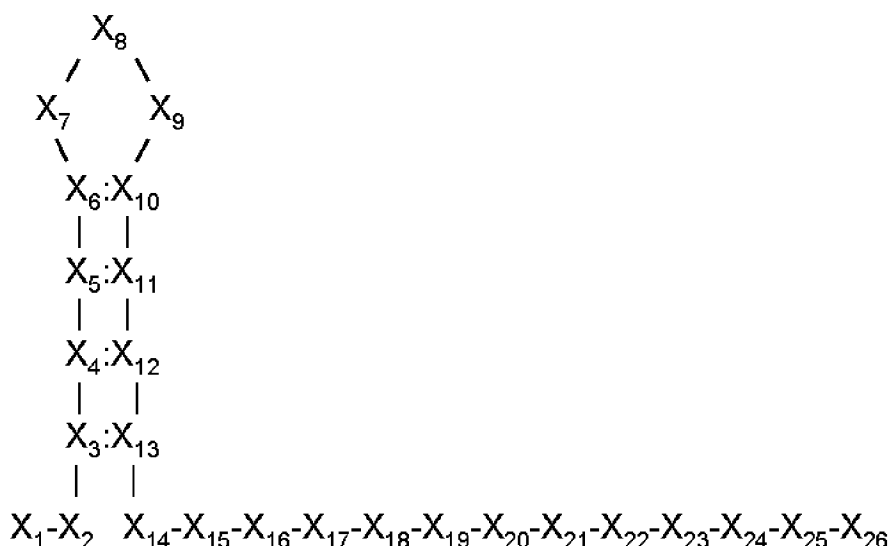
In addition, Applicant's attempt to amend the specification to delete nucleotide sequences, in order to comply with 37 CFR 1.821-1.825 is noted. However, as discussed in the previous Office action (page 5), figure 2 and paragraph [0059] *also* disclose a nucleotide sequence.

As discussed in MPEP 2422.02: "It should be noted, though, that when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings."

Therefore, Applicant will have to submit a Sequence Listing in compliance with 37 CFR 1.821-1.825, as discussed in the previous Office action, or else amend the drawing (figure 2) and paragraph [0059] to remove the sequence. For example, Applicant may remove figure 2 and corresponding text from the specification altogether,

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or draw the secondary structure without the sequence and remove the sequence from paragraph [0059]:



### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-5, 11, 12 and 14-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is noted that all claims depend directly or indirectly on claim 5. The preamble for claim 5 clearly recites "A scalable process for...the separation of a desired recombinant polymerase from undesired nucleic acid", but the body of the claim still recites "exposing purine bases present within either the desired nucleic acid product or

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undesired nucleic acid" (lines 4 and 5, emphasis provided). It is respectfully pointed out that there is no "desired nucleic acid" in this claim.

Furthermore, Applicant's amendment at lines 9-11 ("capture of the desired recombinant polymerase by a technique selective for single-strandedness") does not make any sense. A recombinant polymerase does not comprise single-stranded nucleic acid (or any nucleic acid for that matter); a recombinant polymerase is a protein. It is respectfully pointed out that the embodiment for purifying polymerase as described in the specification is to capture the undesired nucleic acid (e.g. contaminating genomic DNA) on IMAC, separating the IMAC matrix with the bound nucleic acid from the sample, leaving behind the purified polymerase. The polymerase is *not captured*. Nor is it understood how one *could* capture a polymerase by a method selective for nucleic acid single-strandedness.

Because all claims depend ultimately from claim 5, they are rejected for the same reasons. Furthermore, the claim in its current form cannot be searched over the prior art because of the inconsistencies noted above.

In order to assist the Applicant, the examiner has taken the liberty of drafting a set of claims drawn to the embodiment of purifying a polymerase, which Applicant may wish to consider. The examiner would normally have attempted to contact Applicant's representative and set up an examiner's amendment. However, since Applicant must also address the sequence compliance issue (figure 2), the suggested claims were

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included in this Office action. The suggested claims are (note numbering begins with "new" claim 26):

26. A method for separating a polymerase from nucleic acid in a sample comprising:

treating the sample to expose purine bases present in the nucleic acid by a process selected from the group consisting of thermal denaturation, alkaline denaturation and restriction enzyme digestion yielding single-stranded overhangs;

capturing the exposed purine bases of the nucleic acid on a metal chelate matrix, wherein the polymerase does not bind the metal chelate matrix;

separating the polymerase from the metal chelate matrix; and

recovering the polymerase, thereby separating the polymerase from the nucleic acid.

27. The method of claim 26 wherein the polymerase is a thermostable polymerase.

28. The method of claim 27 wherein the polymerase is Taq polymerase.

29. The method of claim 26 wherein the nucleic acid is genomic DNA.

30. The method of claim 26 wherein the sample is a cell lysate.

31. The method of claim 26 wherein the separation is achieved using multi-channel plates.

32. The method of claim 26 wherein the separation is achieved using magnetic particles.

33. The method of claim 26 wherein multiple samples are treated in parallel fashion.

34. The method of claim 26 wherein the metal chelate matrix comprises Cu(II).

35. The method of claim 26 wherein exposing is performed by thermal denaturation followed by quenching in a high salt buffer.

36. The method of claim 34 wherein the high salt buffer comprises 20 mM HEPES and 500 mM NaCl.

37. The method of claim 26 wherein exposing is performed by thermal denaturation followed by rapid cooling.

Should Applicant find these claims acceptable, Applicant should address the sequence compliance issue (figure 2), cancel claims 1-25, and submit the claims above as an after-final amendment, in which case the amendment will be entered.

The examiner would point out that Applicant's last amendment to claim 5 shifted the focus from methods "selective for exposed purine bases" (of which Applicant has only disclosed one, i.e. IMAC) to methods "selective for single-strandedness". If Applicant wishes to pursue this broader aspect, and submits an after-final amendment

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correcting the deficiency under 35 USC 112, 2nd paragraph discussed above, such that the claim could then be searched over the prior art, such an amendment would not be entered as it would require further search and consideration (for methods based on capture techniques selective for single-strandedness).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **SAMUEL C. WOOLWINE** whose telephone number is (571)272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel Woolwine/  
Primary Examiner, AU 1637